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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/701,437 | 03/02/2001 | Thomas Charles Elleman | 50179-086 | 9960 |

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| EXAMINER |
|---|
| ALLEN, MARIANNE P |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1631 | |

DATE MAILED: 01/21/2003 12

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/701,437 | ELLEMAN ET AL. | |
| | Examiner | Art Unit | |
| | Marianne P. Allen | 1631 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *17 December 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-23 and 54-56* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-23 and 54-56* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *17 December 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

## DETAILED ACTION

Upon further consideration of the claims and rejections of record, finality of the rejection of the last Office action is withdrawn. All rejections set forth in the prior Office action are withdrawn in view of the new ground(s) of rejection set forth below.

Applicant's amendment after final rejection submitted 12/17/02 (Paper No. 11) has been entered.

Claims 24-53 have been cancelled. Claims 1-23 and 54-56 are under consideration by the examiner.

### *Specification*

This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

### *Claim Rejections - 35 USC § 112*

Claims 1-23 and 54-56 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This is an enablement rejection.

In *In re Wands* (8 USPQ2d 1400 (CAFC 1988)) the CAFC considered the issue of enablement in molecular biology. The CAFC summarized eight factors to be considered in a determination of "undue experimentation." These factors include: (a) the quantity of experimentation necessary; (b) the amount of direction or guidance presented; (c) the presence or absence of working examples; (d) the nature of the invention; (e) the state of the prior art; (f) the relative skill of those in the art; (g) the predictability of the art; and (h) the breadth of the claims.

The specification discloses determining a 3-D structure for a portion of the EGF receptor by comparative modeling from an IGF receptor 3-D structure. The IGF receptor structure was also modeled. The claims are directed to designing or selecting a compound where the compound designed has a particular property. The specification exemplifies no modeling of any molecule nor does the specification disclose any compounds meeting the structural and functional limitations required by the claims. As written, the claims recite the step of assessing the stereochemical complementarity between a compound and a recited molecule, obtaining the compound, and testing the compound. Note that the claims do not recite that a particular level of stereochemical complementarity is required before obtaining and testing. That is, the claim can be considered to be effectively no different from obtaining and testing all potential compounds as all assessed compounds will be obtained and tested. In addition, the specification provides no guidance as to the stereochemical complementarity (by degree or to which particular portion(s) of the molecule) required to get a molecule with the recited functional limitation. For example, what degree of stereochemical complementarity and to which amino acids does the compound need to have to have a $K_I$ of less than $10^{-6}$ M? (See claim 21.) It is unknown and cannot be predicted from the information presented in the specification.

In particular, claim 1 requires that the compound bind to any molecule of the EGF receptor family (see page 4 for the large number of receptors encompassed) and modulate any activity mediated by the molecule (particular activity of the molecule unknown or unspecified by the claim). What activity? Which receptor?

In particular, claim 1, part (ii), recites using "one of more subsets of said amino acids related to the coordinates shown in Figure 6 by whole body translations and/or rotations." The specification provides no guidance on how to do this or which subsets to use.

In particular, claim 18 requires designing or selecting a molecule which increases an activity mediated by a molecule of the EGF receptor family. What activity? Which receptor?

In particular, claim 19 requires designing or selecting a molecule which decreases an activity mediated by a molecule of the EGF receptor family. What activity? Which receptor?

Undue experimentation would be required to practice the claimed invention as the specification provides no examples and no guidance as how to design molecules resulting in the required properties, the breadth of the claims is very large, and there has been no success in the art in identifying such compounds (see specification at page 27, lines 15-18, and page 26, lines 30-33). Disclosure of using well known computer programs for modeling (see pages 10, 13-14, 17, 21-22, and 27-28) cannot be considered guidance for designing or selecting compounds with particular properties. This is an invitation to experiment. At the very least, one using these programs would have to make decisions with respect to choosing the particular amino acids to consider for assessing stereochemical complementarity, determining what levels of stereochemical complementarity are meaningful, and exercising judgment with respect to which compounds to choose for evaluation. This is not routine experimentation.

Claims 1-23 and 54-56 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites "assessing the stereochemical complementarity between the compound and a topographic region of the molecule." While the claim goes on to delineate the identity of the molecule, it is not known what delimits a topographic region. It is unclear if any portion of (i), (ii), or (iii) or the entirety of (i), (ii), or (iii), or only those portions meeting some unknown criteria was intended.

Claims 1-3 recite "substantially as shown" and "forms an equivalent." It is unknown what degree of similarity is required to meet these limitations. It is unknown what three dimensional structures are encompassed by the claims.

Claim 4 refers to the "structure of a topographic region of the molecule as depicted in Figure 5." Figure 5 is a superposition of the two models of the L1 and S1 domain and of the L2 and S2 domains onto the structure of the first three domains of the IGF-1 receptor. As such, it is unclear what part of the molecule in Figure 5 is being referred to. It is unclear what delimits a topographic region.

In addition, claim 5 discusses the end product (the product designed or selected) without clearly modifying the method steps to result in the desired product. That is, it does not clearly further limit part (A) of claim 1. See also claims 6-23.

Claim 5 recites "to make close contact." It is unknown what level of contact is required to meet this limitation. In addition, Figures 7, 8, and 9 are part of the model polypeptide fold of the L1 and S1 domains of the EGF receptor. The figures don't clearly show the amino acid residues intended to meet the limitation of "at the surface of the molecule lining a groove region." It is not known whether some particular amino region or some portion of this specific three dimensional structure was intended to be a limitation of this claim.

Claims 6-9 and 10-12 recite "such that it can interact." It is not known what is considered to meet this limitation. What degree of interaction is required?

Claim 14 is unclear in that it cannot be determined if the compound must bind to all or some of the named amino acid positions in (i) or all or some of the named amino acid positions in (ii), or all or some of the named amino acid positions in (i) and (ii).

Claims 21-23 recite a $K_1$. This appears to be a typographical error for $K_I$.

***Claim Rejections - 35 USC § 103***

Claims 1-23 and 54-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hendry et al. (U.S. Patent No. 5,705,335).

Hendry et al. teaches assessing stereochemical complementarity of a compound to a receptor, obtaining the compound, and assessing it for biological activity. These steps are the only steps required by the claims.

The difference between the prior art and the claimed invention is the recited three dimensional structure information. This information descriptive material stored on or employed by a machine. This information is fed into a known algorithm whose purpose is to compare or modify those data using a series of processing steps that do not impose a change in the processing steps and are thus nonfunctional descriptive material. A method of using a known comparator (e.g. computer modeling techniques known in the prior art to Hendry, see also specification pages 10, 13-14, 17, 21-22, and 27-28 acknowledging known prior art computer modeling techniques) for its known purpose to compare data sets does not become nonobvious merely because new data becomes available for analysis. Nonfunctional descriptive material cannot render nonobvious an invention that would have otherwise been obvious. See *In re*

*Gulack*, 703 F. 2d 1381, 1385 (Fed. Cir. 1983) and MPEP 2106. Applicant is also directed to the Trilateral Project WM4 Report on Comparative Study on Protein 3-dimensional (3-D) Structure Related Claims at http://www.uspto.gov/web/tws/wm4/wm4_3d/report.htm.

***Conclusion***

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen whose telephone number is 703-308-0666. The examiner can normally be reached on Monday-Friday, 8:30 am - 2:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 703-308-4028. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Marianne P. Allen
Primary Examiner
Art Unit 1631

mpa
January 16, 2003